

BOTOX Study Summary

Study title: Multicenter, double-blind, Placebo controlled, Parallel group Safety Study of Pulmonary Function in Patients with Reduced Lung Function Treated with BOTOX Purified Neurotoxin Complex for Focal Upper Limb Post Stroke Spasticity.

Description/ Purpose:

The purpose of this study is to assess the safety of treatment of spasticity (muscle tightness) with BOTOX for patients with reduced lung function. Currently, the FDA has approved BOTOX for treatment of crossed eyes, eyelid twitching, cervical dystonia, and glabellar line, but it has not been approved for spasticity in stroke patients. Although many neurologists have found BOTOX to be effective for reducing spasticity, the FDA requires sufficient proof that this is a safe and effective means of treatment. This clinical trial was mandated in order for BOTOX to become an FDA approved drug for this treatment.

Participants of the study receive 2 treatments of BOTOX; one in the beginning and another midway through their study visits. There are a total of 9 visits over 32 weeks. At each visit, a pulmonary function exam is administered and patients' level of spasticity is assessed.

Stroke is a highly debilitating disorder and approximately a third of all stroke patients developed spasticity (muscle tightness) in the upper and/or lower limbs to the degree that the limb is completely immovable. In preliminary studies of BOTOX, it has been shown that this treatment restores a considerable degree of mobility. LMC's Stroke Team supports treatment with BOTOX and is actively working towards FDA approval.

Main Inclusion Criteria:

1. Must be an adult patient at least 18 years of age
2. Must have had a stroke at least 6 months ago
3. Must exhibit spasticity from the stroke in upper limb
4. Must have respiratory problems
5. Must not have used BOTOX previously for any condition